EXHIBIT O

September 15, 2015

Expert Report of Shelby F. Thames, Ph.D.

Prepared for

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

Mullins, et al. v. Ethicon, Inc., et al.	*2:12-cv-02952*
Sprout, et al. v. Ethicon, Inc., et al.	*2:12-cv-07924*
Iquinto v. Ethicon, Inc., et al.	*2:12-cv-09765*
Daniel, et al. v. Ethicon, Inc., et al.	*2:13-cv-02565*
Dillon, et al. v. Ethicon, Inc., et al.	*2:13-cv-02919*
Webb, et al. v. Ethicon, Inc., et al.	*2:13-cv-04517*
Martinez v. Ethicon, Inc., et al.	*2:13-cv-04730*
McIntyre, et al. v. Ethicon, Inc., et al.	*2:13-cv-07283*
Oxley v. Ethicon, Inc., et al.	*2:13-cv-10150*
Atkins, et al. v. Ethicon, Inc., et al.	*2:13-cv-11022*
Garcia v. Ethicon, Inc., et al.	*2:13-cv-14355*
Lowe v. Ethicon, Inc., et al.	*2:13-cv-14718*
Dameron, et al. v. Ethicon, Inc., et al.	*2:13-cv-14799*
Vanbuskirk, et al. v. Ethicon, Inc., et al.	*2:13-cv-16183*
Mullens, et al. v. Ethicon, Inc., et al.	*2:13-cv-16564*
Shears, et al. v. Ethicon, Inc., et al.	*2:13-cv-17012*
Javins, et al. v. Ethicon, Inc., et al.	*2:13-cv-18479*
Barr, et al. v. Ethicon, Inc., et al.	*2:13-cv-22606*
Lambert v. Ethicon, Inc., et al.	*2:13-cv-24393*
Cook v. Ethicon, Inc., et al.	*2:13-cv-29260*
Stevens v. Ethicon, Inc., et al.	*2:13-cv-29918*
Harmon v. Ethicon, Inc., et al.	*2:13-cv-31818*
Snodgrass v. Ethicon, Inc., et al.	*2:13-cv-31881*

Miller v. Ethicon, Inc., et al.	*2:13-cv-32627*
Matney, et al. v. Ethicon, Inc., et al.	*2:14-cv-09195*
Jones, et al. v. Ethicon, Inc., et al.	*2:14-cv-09517*
Humbert v. Ethicon, Inc., et al.	*2:14-cv-10640*
Gillum, et al. v. Ethicon, Inc., et al.	*2:14-cv-12756*
Whisner, et al. v. Ethicon, Inc., et al.	*2:14-cv-13023*
Tomblin v. Ethicon, Inc., et al.	*2:14-cv-14664*

I have been asked to analyze Ethicon's Gynecare TVT medical device used for the treatment of stress urinary incontinence and offer opinions concerning claims that the TVT mesh used in Ethicon's product is not suitable for implantation. I have analyzed several other claims involving Ethicon's TVT devices used for the treatment of stress urinary incontinence. Accordingly, I have included in this report my analyses of these products. I have also included in this report critiques of other expert reports offered in this and other cases in which Ethicon's TVT products have been at issue.

Ethicon's TVT product is made of Prolene mesh. Prolene is the Ethicon brand name for its mesh material. Chemically, Prolene consists of polypropylene plus the addition of five highly proprietary additives as discussed herein. Where I refer to polypropylene used in Ethicon's mesh, I am referring to the specific polypropylene and proprietary additives that make this mesh different from mesh marketed by other manufacturers. All my opinions herein are offered to a reasonable degree of scientific certainty.

I have been asked to do the following:

- Address the issues of Ethicon's TVT as a material for use in the human body, its suitability for *in vivo* use considering its chemical and physical properties, propensity for degradation, material strength and viability, as well as longevity.

A copy of my Curriculum Vitae is attached as Appendix A. The materials I reviewed and/or relied upon in connection with the preparation of this report are listed in Appendix B. I am being compensated for my work in this matter at a rate of $400.00/hour.

In addition, I have directed the work performed by Kevin L. Ong, Ph.D., P.E. regarding cleaning, inspecting, testing and analyzing mesh explants, and I further rely upon the facts, opinions and data reflected in his expert reports. I also rely on my prior testing, reports, and appendices prepared in this litigation.

Ethicon's TVT device made from Prolene is suitable for its intended use. Polypropylene (PP) has been used in medical devices for decades, and for good reason.[1,2,3] It is a polymeric species of the propylene monomer and is a durable, thermoplastic polymer composed of carbon and hydrogen. Polypropylene offers mechanical properties of durability and elasticity and is the lightest major plastic with a density of 0.905 g/ml and the crystallizability of isotactic polypropylene makes it the polymer of choice for properties of commercial interest.[4,5]

- Figure 9a-9e[291] are transmission microscopy data for a non-Ethicon product to which I will not respond.

The significant and extensive volume of incorrect and unsupported conclusions, and lack of chemical controls by Dr. Iakovlev proves he has used fundamentally flawed methodologies in his mis-characterization of Prolene.

I have reviewed the July, 2015 paper entitled ‘Degradation of polypropylene *in vivo*: A microscopic analysis of meshes explanted from patients’.[292] This paper purports to prove degradation via staining of polypropylene meshes based solely on microscopic techniques. There is no chemical evidence of any degradation and the stain methodologies utilized are not based on sound, scientific principles and experimentation. Polypropylene does not accept stain.

Review of Dr. Scott Guelcher’s Oxidation Study

I have reviewed FTIR, SEM, and XPS data collected by Dr. Scott Guelcher in which he attempts to oxidize a polypropylene standard and TVT mesh with a mixture of cobalt chloride ($CoCl_2$) and hydrogen peroxide (H_2O_2). Even though this method is reported to be an aggressive oxidation environment[293] NO OXIDATION of any TVT devices could be determined by FTIR and XPS, and thus supports my contention that Prolene is a highly stable molecule and does not oxidize or degrade *in vivo*. Limited oxidation is shown in only two polypropylene control samples which do not contain antioxidants, unlike Ethicon’s TVT device properly formulated with two, highly effective antioxidants.

The FTIR spectra of Figure 20 are taken from Dr. Guelcher’s data collected during his cobalt chloride ($CoCl_2$) and hydrogen peroxide (H_2O_2) oxidation experiment, and supports my opinion that Prolene is resistant to oxidation. For instance, no carbonyl groups were formed during the oxidation experiment and confirms the exceptional stability of Prolene to an oxidation environment. The spectra below in Figure 20 show the 4 week polypropylene (PP) control sample (blue spectra) overlaid with the 4 week TVT sample (red spectra). Dr. Guelcher reports oxidation of the un-stabilized PP sample evidenced by the peak at 1736 cm^{-1}. However, no such peak is present in the TVT sample subjected to the same oxidation medium.

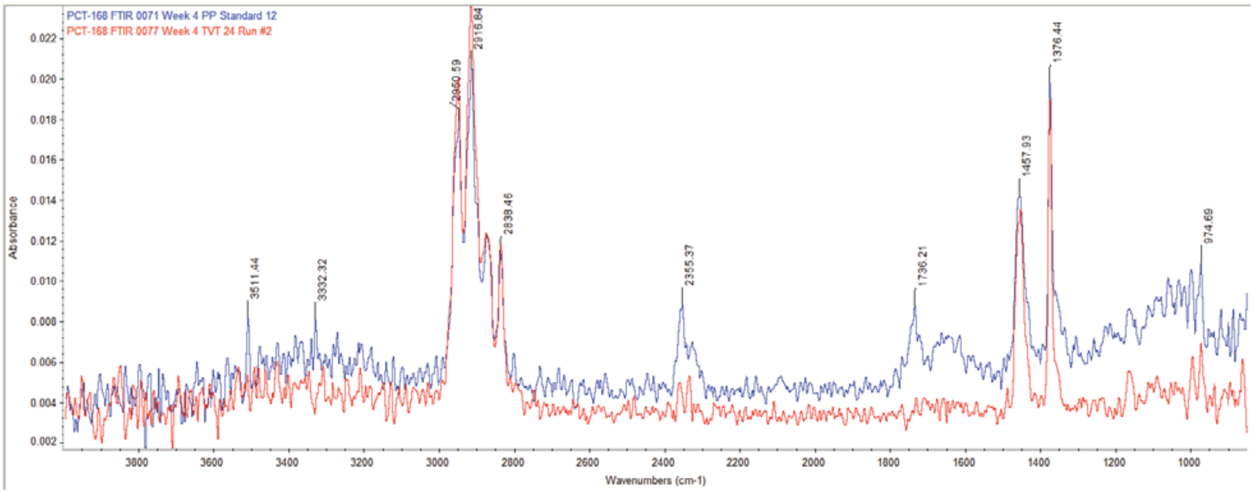

Figure 20. FTIR overlay of PP standard and TVT sample after 4 weeks in $CoCl_2/H_2O_2$.

Dr. Guelcher further opines in the article entitled Oxidative Degradation of Polypropylene Pelvic Mesh In Vitro,[294] that oxidation is present based on an FTIR spectrum of TVT at 5 weeks, however no 5 week control spectrum is provided. His experimental data is not provided in sufficient detail to prove these claims.

My inspection of his SEM photomicrographs suggests that the fibers were surrounded by deposited chemicals as their appearance is far different from the work of Dr. MacLean of Exponent.[295] Moreover, his manuscript was void of any experimental efforts to remove the oxidation medium from the fiber surfaces. Simply rinsing in DI water is not sufficient. Dr. Guelcher's SEM analyses are likewise inconclusive, as they show nothing indicative of TVT mesh oxidation. While there are some contrast variation of the individual fibers surfaces, these are likely the results of $CoCl_2/H_2O$ deposited residues on the fiber surface during the drying step, in preparation for SEM analysis. These deposits could have been easily characterized by energy dispersive X-ray (EDS) analysis while being imaged in the SEM, but no such data was provided. In addition, the data set continues through a six week period for TVT samples, while the polypropylene control experimentation, and thus data collection, is provided for only four weeks. This represents a flawed, inconsistent, and inadequate scientific approach when test specimens, and experimental controls are not subjected to the same time period and treatment regime. In any event, Prolene was not oxidized by the $CoCl_2/H_2O$ blend.

Dr. Guelcher's 'Methods' section regarding sample handling states that 'every week, 6 samples were removed, washed in DI water, and dried for analysis.'[296] Dr. Guelcher further notes that the samples were analyzed by XPS and FTIR in order to determine the presence of hydroxyl groups (-OH) and terminal C=O end groups.

Further analyses by X-ray photoelectron spectroscopy (XPS) analyses were performed in an effort to show Prolene oxidation. However, the experimental data does not support oxidation. The experimental data was collected by Dr. Bridget Rogers via

XPS.[297] A review of Roger's Table 1 XPS data (Figure 21) for TVT is clearly flawed and in error. For instance, all samples of TVT should exhibit carbonyl configurations (C=O) as Prolene possesses DLTDP and Ca-Stearate, both of which are carbonyl (C=O) containing chemicals. However, Dr. Rogers found only 4 of 17 samples showed C=O configurations. These data clearly confirms the methodology used is flawed and in error, given all 17 samples of TVT possess carbonyl containing chemicals, and consequently the XPS data should confirm the presence of C=O for all samples, but does not. That Guelcher used this analytical technique to confirm C=O presence is proof positive he does not understand Prolene's chemical composition, yet he is opining on its potential degradation tendencies.

Table 1. Fraction of carbon atoms bonded in the R-C-OOH and C=O configurations on TVT samples

Week	TVT					
	First Sample		Second Sample		Third Sample	
	R-C-OOH	C=O	R-C-OOH	C=O	R-C-OOH	C=O
0	0	0				
1	0	0	0	0.0135	0	0
2	0	0	0	0	0	0
3	0	0	0.0088	0	0	0.00180
4	0.0106	0	0	0	0	0
5	0.4874	0	0.5054	0.0062	0	0.0084
6	0.0051	0				

Figure 21. Bridget Rogers XPS Data for TVT[298]

Even the polypropylene control pellets subjected to this oxidation do not show a consistent trend in C=O detected via XPS (see Table 2, week 1 Polypropylene Standard data) as noted in Figure 22.

information, documents and materials, and to revise this report following the receipt of additional information and/or materials that have not yet been made available.

Shelby F. Thames, Ph.D.

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